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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date 2-3-03
Publication Date 2-4-03
Certifier A. Corbin

Food and Drug Administration

[Docket No. 00D–1540]

Withdrawal of Draft Guidance for Industry on Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a draft guidance entitled "Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records."

DATES: [*Insert date of publication in the* **Federal Register**.]

FOR FURTHER INFORMATION CONTACT: Randall L. Woods, Center for Drug Evaluation and Research (HFD–324), Food and Drug Administration, Metro Park North I, 7520 Standish Pl., rm. 265, Rockville, MD 20855, 301–827–0065.

SUPPLEMENTARY INFORMATION:

I. Background

On August 21, 2002, FDA announced that it was undertaking a new initiative to enhance FDA's current good manufacturing practice program (the CGMP initiative). This new initiative will focus FDA's resources and regulatory attention on those aspects of manufacturing that pose the greatest risk, ensure that FDA's work does not impede innovation, and enhance the consistency of FDA's regulatory approach among the various components. More

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information on FDA's announcement of this new initiative can be found on FDA's Web site at www.fda.gov/bbs/topics/NEWS/2002/NEW00829.html, or a copy of the press release (Ref. 1) may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please reference the docket number found in brackets in the heading of this document.

Under the new initiative, primary responsibility for implementing part 11 (21 CFR Part 11); Electronic Records; Electronic Signatures has shifted to the Center for Drug Evaluation and Research, with continued involvement from other Centers and the Office of Regulatory Affairs.

On November 12, 2002 (67 FR 68674), the agency issued a draft guidance for industry entitled "Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records." The agency wishes to limit the time spent by industry reviewing and commenting on the guidance, which may no longer represent FDA's approach under the CGMP initiative. The agency may decide to reissue the draft guidance once it has reviewed it under the CGMP initiative.

II. Reference

The following reference is on display at the Dockets Management Branch (see section I of this document) and may be seen by interested parties between 9 a.m. and 4 p.m., Monday through Friday.

1. U.S. Food and Drug Administration press release, "FDA Unveils New Initiative To Enhance Pharmaceutical Good Manufacturing Practices," August 21, 2002.

Dated: 1/28/03
January 28, 2003.

Margaret M. Dotzel,
Assistant Commissioner for Policy.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date 2-3-03
Publication Date 2-4-03
Certifier A. Corbin

Food and Drug Administration

[Docket No. 02N–0534]

Medical Device User Fee and Modernization Act of 2002; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is establishing a public docket to obtain input on implementation of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). FDA is establishing this docket in order to provide an opportunity for all interested persons to provide information and share views on the implementation of MDUFMA.

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–2974.

SUPPLEMENTARY INFORMATION: MDUFMA (Public Law 107–250) amends the Federal Food, Drug, and Cosmetic Act to provide FDA important new

responsibilities, resources, and challenges. MDUFMA was signed into law October 26, 2002. MDUFMA has three particularly significant provisions:

• User fees for premarket reviews. Premarket approval applications (PMAs), product development protocols (PDPs), biologics license application (BLAs), premarket reports, certain supplements, and 510(k)s are now subject to fees. The revenues from these fees, and from additional appropriations for infrastructure, will allow FDA to pursue a set of ambitious performance goals that will provide patients earlier access to safe and effective technology, and will provide more interactive and rapid review to the medical device industry. A small business (sales and receipts of $30 million or less) may pay a reduced fee.

• Establishment inspections may be conducted by accredited persons (third-parties) under carefully prescribed conditions.

• New regulatory requirements for reprocessed single-use devices, including provisions establishing a new category of premarket submission, the premarket report, and provisions requiring the submission of additional data on devices now being reprocessed.

MDUFMA makes several other significant changes that are less complex or have a narrower scope than the major changes discussed previously. These include the following:

• The review of combination products (products that combine elements of devices, drugs, or biologics) will be coordinated by a new office in the Office of the Commissioner of Food and Drugs.

• Electronic labeling is authorized for prescription devices intended to be used in health care facilities.

• FDA may require electronic registration of device establishments, when feasible.

• The law now explicitly provides for modular review of PMAs.

• New provisions concerning devices intended for pediatric use, including provisions for pediatric experts on advisory panels and the development of guidance for clinical trials involving pediatric populations.

• The manufacturer of a device must be identified on the device itself, with certain exceptions.

A letter from the Secretary of Health and Human Services that accompanies the user fee legislation sets forth the performance goals the agency has pledged to meet over the next 5 years. These goals represent the improvements FDA's device review program can achieve, monitor, and meet with industry cooperation. To help meet these performance goals, FDA will need to develop clear definitions of terms such as "panel-track supplement," "180-day supplement," and "real-time supplement." The agency will also need to develop a policy to define when bundling multiple devices, device modifications, or indications for use into a single submission is appropriate versus when separate applications should be submitted.

FDA invites interested persons to submit comments on any or all of the previous issues, as well as other provisions of the new law. (A copy of the statute is available on the agency's MDUFMA Web site at http://www.fda.gov/cdrh/mdufma/index.html). FDA hopes this docket will become an important tool for receiving information from interested parties and for public availability of that information. In the future, FDA expects to use its MDUFMA Web site to request input to the docket from stakeholders on a variety of specific questions and issues related to MDUFMA.

At this time, the agency is particularly interested in receiving comments from stakeholders about several provisions that must be immediately implemented to track and monitor the performance goals FDA has pledged to meet over the next few years. Specifically, the agency is seeking input on the following: (1) Defining the various types of PMA supplements; (2) implementing the modular review program for PMAs; (3) establishing a bundling policy to determine when it is appropriate to bundle multiple devices, device modifications, or indications for use into a single submission; and (4) gathering information for the pediatric device guidance document.

On a related matter, MDUFMA also provides for the education and training of stakeholders to assist the agency in developing training programs. FDA invites comments on: (1) Possible subject matter or areas to be included in training programs for FDA employees or industry and (2) subject matter or courses that industry would be willing to provide to FDA employees. Past examples would include sterilization.

FDA will consider all information and views that it receives during the implementation process. FDA will continue to work with interested parties through a variety of means to obtain as much information as possible to assist in the implementation process.

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments. Submit a single copy of electronic comments to http://www.fda.gov/dockets/ecomments or two copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 1/29/03
January 29, 2003.

Margaret M. Dotzel,
Assistant Commissioner for Policy.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

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